

House File 233 - Introduced

HOUSE FILE 233
BY COMMITTEE ON HUMAN
RESOURCES

(SUCCESSOR TO HSB 26)

A BILL FOR

1 An Act relating to the use of step therapy protocols for
2 prescription drugs by health carriers, health benefit
3 plans, and utilization review organizations, and including
4 applicability provisions.

5 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

1 Section 1. LEGISLATIVE FINDINGS. The general assembly
2 finds and declares the following:

3 1. Health carriers, health benefit plans, and utilization
4 review organizations are increasingly making use of step
5 therapy protocols under which covered persons are required to
6 try one or more prescription drugs before coverage is provided
7 for another prescription drug selected by the covered person's
8 health care professional.

9 2. Such step therapy protocols, where they are based on
10 well-developed scientific standards and administered in a
11 flexible manner that takes into account the individual needs
12 of covered persons, can play an important part in controlling
13 health care costs.

14 3. In some cases, requiring a covered person to follow
15 a step therapy protocol may have adverse and even dangerous
16 consequences for the covered person, who may either not realize
17 a benefit from taking a particular prescription drug or may
18 suffer harm from taking an inappropriate prescription drug.

19 4. Without uniform policies in the state for step therapy
20 protocols, all covered persons may not receive equivalent or
21 the most appropriate treatment.

22 5. It is imperative that step therapy protocols in the state
23 preserve the health care professional's right to make treatment
24 decisions that are in the best interest of the covered person.

25 6. It is a matter of public interest that the general
26 assembly require health carriers, health benefit plans, and
27 utilization review organizations to base step therapy protocols
28 on appropriate clinical practice guidelines or published peer
29 review data developed by independent experts with knowledge
30 of the condition or conditions under consideration; that
31 covered persons be excepted from step therapy protocols when
32 inappropriate or otherwise not in the best interest of the
33 covered persons; and that covered persons have access to a
34 fair, transparent, and independent process for allowing a
35 covered person or a health care professional to request an

1 exception to a step therapy protocol when the covered person's
2 health care professional deems appropriate.

3 Sec. 2. NEW SECTION. 514F.7 Use of step therapy protocols.

4 1. *Definitions.* For the purposes of this section:

5 a. "*Authorized representative*" means the same as defined in
6 section 514J.102.

7 b. "*Clinical practice guidelines*" means a systematically
8 developed statement to assist health care professionals and
9 covered persons in making decisions about appropriate health
10 care for specific clinical circumstances and conditions.

11 c. "*Clinical review criteria*" means the same as defined in
12 section 514J.102.

13 d. "*Covered person*" means the same as defined in section
14 514J.102.

15 e. "*Health benefit plan*" means the same as defined in
16 section 514J.102.

17 f. "*Health care professional*" means the same as defined in
18 section 514J.102.

19 g. "*Health care services*" means the same as defined in
20 section 514J.102.

21 h. "*Health carrier*" means the same as defined in section
22 514J.102.

23 i. "*Medical necessity*" means health care services and
24 supplies that under the applicable standard of care are
25 appropriate for any of the following:

26 (1) To improve or preserve health, life, or function.

27 (2) To slow the deterioration of health, life, or function.

28 (3) For the early screening, prevention, evaluation,
29 diagnosis, or treatment of a disease, condition, illness, or
30 injury.

31 j. "*Step therapy override exception*" means a step therapy
32 protocol should be overridden in favor of immediate coverage of
33 the prescription drug selected by a health care professional.
34 This determination is based on a review of the covered person's
35 or health care professional's request for an override, along

1 with supporting rationale and documentation.

2 *k. "Step therapy protocol"* means a protocol or program that
3 establishes a specific sequence in which prescription drugs for
4 a specified medical condition and medically appropriate for
5 a particular covered person are covered under a pharmacy or
6 medical benefit by a health carrier, a health benefit plan, or
7 a utilization review organization, including self-administered
8 drugs and drugs administered by a health care professional.

9 *l. "Utilization review"* means a program or process by which
10 an evaluation is made of the necessity, appropriateness, and
11 efficiency of the use of health care services, procedures, or
12 facilities given or proposed to be given to an individual.
13 Such evaluation does not apply to requests by an individual or
14 provider for a clarification, guarantee, or statement of an
15 individual's health insurance coverage or benefits provided
16 under a health benefit plan, nor to claims adjudication.
17 Unless it is specifically stated, verification of benefits,
18 preauthorization, or a prospective or concurrent utilization
19 review program or process shall not be construed as a guarantee
20 or statement of insurance coverage or benefits for any
21 individual under a health benefit plan.

22 *m. "Utilization review organization"* means an entity that
23 performs utilization review, other than a health carrier
24 performing utilization review for its own health benefit plans.

25 2. *Establishment of step therapy protocols.*

26 *a.* A health carrier, health benefit plan, or utilization
27 review organization shall do all of the following when
28 establishing a step therapy protocol:

29 (1) Use clinical review criteria based on clinical practice
30 guidelines that meet all of the following requirements:

31 (a) Recommend that particular prescription drugs be taken
32 in the specific sequence required by the step therapy protocol.

33 (b) Are developed and endorsed by a multidisciplinary panel
34 of experts that manages conflicts of interest among members
35 of the panel's writing and review groups by doing all of the

1 following:

2 (i) Requiring members to disclose any potential conflicts
3 of interest with entities, including health carriers,
4 health benefit plans, utilization review organizations, and
5 pharmaceutical manufacturers, and requiring members to recuse
6 themselves from voting if there is a conflict of interest.

7 (ii) Using a methodologist to work with the panel's writing
8 groups to provide objectivity in data analysis and ranking of
9 evidence through the preparation of evidence tables and by
10 facilitating consensus.

11 (iii) Offering opportunities for public review and
12 comments.

13 (c) Are based on high-quality studies, research, and
14 medical practice.

15 (d) Are created through an explicit and transparent process
16 that does all of the following:

17 (i) Minimizes biases and conflicts of interest.

18 (ii) Explains the relationship between treatment options
19 and outcomes.

20 (iii) Rates the quality of the evidence supporting the
21 recommendations.

22 (iv) Considers relevant patient subgroups and preferences.

23 (e) Are continually updated through a review of new
24 evidence, research, and newly developed treatments.

25 (2) Take into account the needs of atypical covered person
26 populations and diagnoses when establishing clinical review
27 criteria.

28 (3) Notwithstanding subparagraph (1), peer-reviewed
29 publications may be substituted for the use of clinical
30 practice guidelines in establishing a step therapy protocol.

31 *b.* This subsection shall not be construed to require
32 health carriers, health benefit plans, utilization review
33 organizations, or the state to establish a new entity to
34 develop clinical review criteria for step therapy protocols.

35 *c.* A health carrier, health benefit plan, or utilization

1 review organization shall, upon written request of an insured
2 or prospective insured, provide specific written clinical
3 review criteria relating to a particular condition or disease,
4 including clinical review criteria relating to a request for a
5 step therapy override exception and, where appropriate, other
6 clinical information which the health carrier, health benefit
7 plan, or utilization review organization might consider in its
8 utilization review or in making a determination to approve
9 or deny a request for a step therapy override exception,
10 including a description of how the information will be used in
11 the utilization review process or in making a determination
12 to approve or deny a request for a step therapy override
13 exception. However, to the extent that such information is
14 proprietary to the health carrier, health benefit plan, or
15 utilization review organization, the insured or prospective
16 insured shall only use the information for the purposes of
17 assisting the insured or prospective insured in evaluating the
18 covered services provided by the health carrier, health benefit
19 plan, or utilization review organization. Such clinical review
20 criteria and other clinical information shall also be made
21 available to a health care professional, upon written request
22 made by the health care professional on behalf of an insured
23 or prospective insured.

24 3. *Exceptions process transparency.*

25 a. When coverage of a prescription drug for the
26 treatment of any medical condition is restricted for use
27 by a health carrier, health benefit plan, or utilization
28 review organization through the use of a step therapy
29 protocol, the covered person and the prescribing health
30 care professional shall have access to a clear, readily
31 accessible, and convenient process to request a step therapy
32 override exception. A health carrier, health benefit plan, or
33 utilization review organization may use its existing medical
34 exceptions process to satisfy this requirement. The process
35 used shall be easily accessible on the internet site of the

1 health carrier, health benefit plan, or utilization review
2 organization.

3 *b.* A step therapy override exception shall be approved
4 expeditiously by a health carrier, health benefit plan,
5 or utilization review organization if any of the following
6 circumstances apply:

7 (1) The prescription drug required under the step therapy
8 protocol is contraindicated or is likely to cause an adverse
9 reaction or physical or mental harm to the covered person.

10 (2) The prescription drug required under the step therapy
11 protocol is expected to be ineffective based on the known
12 clinical characteristics of the covered person and the known
13 characteristics of the prescription drug regimen.

14 (3) The covered person has tried the prescription drug
15 required under the step therapy protocol while under the
16 covered person's current or a previous health benefit plan,
17 or another prescription drug in the same pharmacologic class
18 or with the same mechanism of action, and such prescription
19 drug was discontinued due to lack of efficacy or effectiveness,
20 diminished effect, or an adverse event.

21 (4) The prescription drug required under the step therapy
22 protocol is not in the best interest of the covered person,
23 based on medical necessity.

24 (5) The covered person is stable on a prescription drug
25 selected by the covered person's health care professional for
26 the medical condition under consideration while on the current
27 or a previous health benefit plan.

28 *c.* Upon approval of a step therapy override exception, the
29 health carrier, health benefit plan, or utilization review
30 organization shall expeditiously authorize coverage for the
31 prescription drug selected by the covered person's prescribing
32 health care professional.

33 *d.* A health carrier, health benefit plan, or utilization
34 review organization shall make a determination to approve or
35 deny a request for a step therapy override exception within

1 seventy-two hours of receipt of the request for an exception or
2 appeal of a denial of such a request. In cases where exigent
3 circumstances exist, a health carrier, health benefit plan, or
4 utilization review organization shall make a determination to
5 approve or deny the request for an exception or appeal of a
6 denial of such a request within twenty-four hours of receipt
7 of the request for an exception or appeal of a denial of such a
8 request. If a determination to approve or deny the request for
9 an exception or appeal of a denial of such a request is not made
10 within the applicable time period, the request for an exception
11 or appeal of a denial of such a request shall be deemed to be
12 approved.

13 e. If a determination is made to deny a request for
14 a step therapy override exception, the health carrier,
15 health benefit plan, or utilization review organization
16 shall provide the covered person or the covered person's
17 authorized representative and the covered person's prescribing
18 health care professional with the reason for the denial and
19 information regarding the procedure to appeal the denial. Any
20 determination to deny a request for a step therapy override
21 exception may be appealed by a covered person or the covered
22 person's authorized representative.

23 f. A health carrier, health benefit plan, or utilization
24 review organization shall uphold or reverse a denial of
25 a request for a step therapy override exception within
26 seventy-two hours of receipt of an appeal of the denial.
27 In cases where exigent circumstances exist as provided in
28 paragraph "d", a health carrier, health benefit plan, or
29 utilization review organization shall make a determination to
30 uphold or reverse a denial of such a request within twenty-four
31 hours of receipt of an appeal of the denial. If the denial of
32 a request for a step therapy override exception is not upheld
33 or reversed on appeal within the applicable time period, the
34 denial shall be deemed to be reversed and the request for an
35 override exception shall be deemed to be approved.

1 *g.* If a denial of a request for a step therapy override
2 exception is upheld on appeal, the health carrier, health
3 benefit plan, or utilization review organization shall
4 provide the covered person or the covered person's authorized
5 representative and the patient's prescribing health care
6 professional with the reason for upholding the denial on appeal
7 and information regarding the procedure to request external
8 review of the denial pursuant to chapter 514J. Any denial of a
9 request for a step therapy override exception that is upheld
10 on appeal shall be considered a final adverse determination
11 for purposes of chapter 514J and is eligible for a request for
12 external review by a covered person or the covered person's
13 authorized representative pursuant to chapter 514J.

14 4. *Limitations.* This section shall not be construed to do
15 either of the following:

16 *a.* Prevent a health carrier, health benefit plan, or
17 utilization review organization from requiring a covered person
18 to try an AB-rated generic equivalent prescription drug prior
19 to providing coverage for the equivalent branded prescription
20 drug.

21 *b.* Prevent a health care professional from prescribing
22 a prescription drug that is determined to be medically
23 appropriate.

24 Sec. 3. APPLICABILITY. This Act is applicable to a health
25 benefit plan that is delivered, issued for delivery, continued,
26 or renewed in this state on or after January 1, 2018.

27

EXPLANATION

28 The inclusion of this explanation does not constitute agreement with
29 the explanation's substance by the members of the general assembly.

30 This bill relates to the use of step therapy protocols
31 for prescription drugs by health carriers, health benefit
32 plans, and utilization review organizations, and includes
33 applicability provisions.

34 The bill includes legislative findings that step therapy
35 protocols are increasingly being used by health carriers,

1 health benefit plans, and utilization review organizations to
2 control health care costs, that step therapy protocols that
3 are based on well-developed scientific standards and flexibly
4 administered can play an important role in controlling health
5 care costs, but that in some cases use of such protocols can
6 have adverse or dangerous consequences for the person for whom
7 the drugs are prescribed. The bill includes findings that
8 uniform policies for the use of such protocols that preserve a
9 health care professional's right to make treatment decisions
10 and that provide for exceptions to the use of such protocols
11 are in the public interest.

12 The bill defines a "step therapy protocol" as a protocol
13 or program that establishes a specific sequence in which
14 prescription drugs for a specified medical condition and
15 medically appropriate for a particular covered person are
16 covered under a pharmacy or medical benefit by a health
17 carrier, a health benefit plan, or a utilization review
18 organization including self-administered drugs and drugs
19 administered by a health care professional.

20 The bill requires that a step therapy protocol be
21 established using clinical review criteria that are based
22 on specified clinical practice guidelines. A step therapy
23 protocol should take into account the needs of atypical
24 populations and diagnoses. The bill does not require a health
25 carrier, health benefit plan, utilization review organization,
26 or the state to establish a new entity to develop clinical
27 review criteria for such protocols.

28 Upon written request of an insured or prospective insured,
29 or upon written request of a health care professional on behalf
30 of such a person, a health carrier, health benefit plan,
31 or utilization review organization shall provide specific
32 written clinical review criteria relating to a particular
33 condition or disease, including criteria relating to a request
34 for a step therapy override exception which might be used in
35 utilization review or in making a determination to approve or

1 deny a request for a step therapy override exception. If the
2 information provided is proprietary the insured or prospective
3 insured shall use it only for purposes of evaluating covered
4 services.

5 The bill also provides that when a step therapy protocol
6 is in use, the person participating in a health benefit plan
7 or the person's prescribing health care professional must
8 have access to a clear, readily accessible, and convenient
9 process to request a step therapy override exception. A "step
10 therapy override exception" means a step therapy protocol
11 should be overridden in favor of immediate coverage of the
12 prescription drug selected by the prescribing health care
13 professional, based on a review of the request along with
14 supporting rationale and documentation. The bill provides that
15 the request for an exception shall be granted if specified
16 circumstances are determined to exist and coverage for the drug
17 selected by the prescribing health care professional shall be
18 authorized.

19 A request for a step therapy override exception must be
20 approved or denied by the health carrier, health benefit plan,
21 or utilization review organization utilizing the step therapy
22 protocol within 72 hours of receipt of the request or appeal of
23 a denial of such a request, or within 24 hours of receipt of the
24 request or appeal of a denial of such a request where exigent
25 circumstances exist. The health carrier, health benefit
26 plan, or utilization review organization can use its existing
27 medical exceptions procedure to satisfy this requirement. If
28 a determination to approve or deny the request or appeal of a
29 denial of such a request is not made within the applicable time
30 period, the request is deemed to be approved.

31 If a determination is made to deny the request for a step
32 therapy override exception, the health carrier, health benefit
33 plan, or utilization review organization shall provide the
34 person making the request with the reason for the denial and
35 information about the procedure to appeal the denial. Any

1 denial of such a request is eligible for appeal.

2 Upon appeal, the health carrier, health benefit plan, or
3 utilization review organization shall make a determination to
4 uphold or reverse the denial within 72 hours, or within 24
5 hours in the case of exigent circumstances, of receiving the
6 appeal. If the denial is not upheld or reversed on appeal
7 within the applicable time period, the denial is deemed to
8 be reversed and the request for an exception is deemed to be
9 approved.

10 If a denial of a request for a step therapy override
11 exception is upheld on appeal, the person making the appeal
12 shall be provided with the reason for upholding the denial
13 on appeal and information regarding the procedure to request
14 external review of the denial pursuant to Code chapter 514J.
15 A denial of a request for such an exception that is upheld on
16 appeal shall be considered a final adverse determination for
17 purposes of Code chapter 514J and is eligible for a request for
18 external review pursuant to Code chapter 514J.

19 The bill shall not be construed to prevent a health carrier,
20 health benefit plan, or utilization review organization from
21 requiring a person to try an AB-rated generic equivalent
22 prescription drug prior to providing coverage for the
23 equivalent branded prescription drug, or to prevent a health
24 care professional from prescribing a prescription drug that is
25 determined to be medically appropriate.

26 The bill is applicable to a health benefit plan that is
27 delivered, issued for delivery, continued, or renewed in this
28 state on or after January 1, 2018.